4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 516, 520, 522, 528, and 558

[Docket No. FDA-2022-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Change of Sponsor; Change of Sponsor Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), and conditionally approved new animal drug applications (cNADAs) during April, May, and June 2022. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to improve the accuracy and readability of the regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs, ANADAs, and cNADAs during April, May, and June 2022, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of

environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room. Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book.

FDA has verified the website addresses as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Table 1.--Original and Supplemental NADAs, ANADAs, and cNADAs Approved During April, May, and June 2022 Requiring Evidence of Safety and/or Effectiveness

Approval date	File No.	Sponsor	Product name	Effect of the action	Public documents	21 CFR Section
April 28, 2022	141-137	Pharmgate, Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405	PENNITRACIN MD (bacitracin Type A medicated article)	Supplemental approval for the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler and replacement chickens	FOI Summary	558.76
June 16, 2022	141-556	Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096	VETMEDIN-CA1 (pimobendan) Chewable Tablets	Conditional approval for the delay of onset of congestive heart failure in dogs with Stage B2 preclinical myxomatous mitral valve disease	FOI Summary	516.1780

Also, FDA is amending the animal drug regulations to reflect approval of supplemental applications, as listed in table 2, to change the marketing status of dosage form antimicrobial animal drug products from over-the-counter (OTC) to veterinary prescription (Rx). These applications were submitted in voluntary compliance with the goals of the FDA Center for Veterinary Medicine's (CVM's) Judicious Use Initiative as identified by guidance for industry #263, "Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter," June 11, 2021 (https://www.fda.gov/media/130610/download).

Table 2.--Supplemental Applications Approved During April, May, and June 2022 to Change the Marketing Status of Antimicrobial Animal Drug Products from OTC to Rx

Approval date	File No.	Sponsor	Product name	21 CFR Section
May 31, 2022	008-769	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	TERRAMYCIN (oxytetracycline hydrochloride) Injectable Solution; LIQUAMYCIN (oxytetracycline hydrochloride) Injectable Solution	522.1662a
June 7, 2022	007-981	Do.	SOXISOL (sulfisoxazole) Tablets	520.2330

II. Changes of Sponsorship

The sponsors of the following approved applications have informed FDA that they have transferred ownership of, and all rights and interest in, the applications to another sponsor, as listed in table 3.

Table 3.-- Changes of Sponsorship During April, May, and June 2022

File No.	Product name	Transferring sponsor	New sponsor	21 CFR Section
119-688	CEFA-TABS (cefadroxil) Tablets	Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096	HQ Specialty Pharma Corp., 120 Rte. 17 North, Suite 130, Paramus, NJ 07652	520.314
140-684	CEFA-DROPS (cefadroxil) Powder for Suspension	Do.	Do.	520.314
141-217	ZEUTERIN (zinc gluconate) Injectable Solution	Ark Sciences, Inc., 1101 East 33rd St., Suite B304, Baltimore, MD 21218	Aiping Pharmaceutical, Inc., 350W Wireless Blvd., Hauppauge, NY 11788	522.2690
141-551	ZENALPHA (medetomidine hydrochloride and vatinoxan hydrochloride) Injectable Solution	Vetcare Oy, P.O. Box 26 (Liedontie 45), Mäntsälä, Uusimaa, 04601, Finland	Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom	522.1338

Following these changes of sponsorship, Ark Sciences, Inc. and Vetcare Oy are no longer the sponsor of an approved application. Accordingly, the drug labeler codes for these firms will be removed from § 510.600 (21 CFR 510.600).

III. Change of Sponsor Address

Anivive Lifesciences, Inc., 3250 Airflite Way, Suite 400, Long Beach, CA 90807 has informed FDA that it has changed its address to 3777 Worsham Ave., Long Beach, CA 90808. As provided in the regulatory text, § 510.600 is amended to reflect this change.

IV. Technical Amendments

FDA is making the following amendments to improve the accuracy of the animal drug regulations:

- 21 CFR 510.600 is amended to remove Ark Sciences, Inc., and Vetcare Oy from the list of sponsors of approved applications and to revise the address for Anivive Lifesciences, Inc. A punctuation change is made in the codified name for Vétoquinol USA, Inc.
- 21 CFR 520.563 is amended to reflect the correct section title for diatrizoate oral solution.
- 21 CFR 520.2640 is amended to reflect sponsors' container contents and the dosage in parts per million of tylosin tartrate soluble powder for use in drinking water of turkeys and swine.
- 21 CFR 522.955 is amended to reflect drug labeler codes of application sponsors and to revise a pathogen name for florfenicol injectable solution in cattle.
- 21 CFR 522.2471 is amended to reflect a revised withdrawal period and human food safety warnings for tilmicosin injectable solution in sheep.
- The heading for Part 528 is revised to reflect a more accurate title.
- 21 CFR 558.95 is amended to reflect revised classes of cattle for use of bambermycins medicated feeds.

- 21 CFR 558.128 is amended to reflect approved incorporation rates for chlortetracycline medicated feeds for cattle.
- 21 CFR 558.342 is amended to reflect all sponsors of approved applications for use of melengestrol medicated feeds in heifers.
- 21 CFR 558.450 is amended to reflect revised residue warnings for use of oxytetracycline medicated feeds in cattle.
- 21 CFR 558.455 is amended to reflect a revised indication for use of oxytetracycline with neomycin in medicated cattle feeds and an updated format.
- 21 CFR 558.575 is amended to reflect approved incorporations rates for use of sulfadimethoxine and ormetoprim in medicated feeds for salmonids and catfish.

V. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C.360b(i)), which requires *Federal Register* publication of "notice[s]… effective as a regulation," of the conditions of use of approved new animal drugs. This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities.

Although denominated a rule pursuant to the FD&C Act, this document does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a "rule of particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as "an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency."

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, and 528

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510, 516, 520, 522, 528, and 558 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. In § 510.600:

a. In the table in paragraph (c)(1), remove the entries for “Ark Sciences, Inc.” and “Vetcare Oy”; revise the entries for “Anivive Lifesciences, Inc.”; and “Vétoquinol USA, Inc.”; and add in alphabetical order an entry for “Aiping Pharmaceutical, Inc.”; and

b. In the table in paragraph (c)(2), add an entry for “011788”; revise the entries for “017030” and “086121”; and remove the entries for “076175” and “086155”.

The revisions and additions read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
Aiping Pharmaceutical, Inc., 350W Wireless Blvd., Hauppauge, NY 11788	011788
* * * * * * *	
Anivive Lifesciences, Inc., 3777 Worsham Ave., Long Beach, CA 90808	086121
* * * * * * *	
Vetoquinol USA, Inc., 4250 N. Sylvania Ave., Fort Worth, TX 76137	017030
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
011788	Aiping Pharmaceutical, Inc., 350W Wireless Blvd., Hauppauge, NY 11788
* * * * * * *	
017030	Vetoquinol USA, Inc., 4250 N. Sylvania Ave., Fort Worth, TX 76137
* * * * * * *	
086121	Anivive Lifesciences, Inc., 3777 Worsham Ave., Long Beach, CA 90808
* * * * * *	

PART 516--NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

3. The authority citation for part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc-1, 360ccc-2, 371.

4. Add § 516.1780 to subpart E to read as follows:

§ 516.1780 Pimobendan.

(a) *Specifications*. Each chewable tablet contains 1.25, 2.5, 5, or 10 milligrams (mg) pimobendan.

(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*--(1) *Amount*. Administer orally at a total daily dose of 0.23 mg per pound (0.5 mg per kilogram) body weight, using a suitable combination of whole or half tablets. The total daily dose should be divided into two portions administered approximately 12 hours apart.

(2) *Indications for use in dogs*. For the delay of onset of congestive heart failure in dogs with Stage B2 preclinical myxomatous mitral valve disease (2019 ACVIM Consensus Statement). Stage B2 preclinical myxomatous mitral valve disease (MMVD) refers to dogs with

asymptomatic MMVD that have a moderate or loud mitral murmur due to mitral regurgitation and cardiomegaly.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

5. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.314 [Amended]

6. In § 520.314, in paragraph (b), remove "000010" and in its place add "042791".

7. In § 520.563, revise the section heading to read as follows:

§ 520.563 Diatrizoate.

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8. In § 520.2330, amend paragraph (c)(3) by adding a sentence to the end of the paragraph.

§ 520.2330 Sulfisoxazole tablets.

*****

(c)***

(3) *** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

9. In § 520.2640, revise paragraphs (a), (b), (e)(2)(i), and (3)(i) to read as follows:

§ 520.2640 Tylosin.

(a) *Specifications*. Each container of soluble powder contains tylosin tartrate equivalent to:

(1) 100 grams (g) tylosin base, or

(2) 256 g tylosin base.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section:

(1) Nos. 016592 and 058198 for use of the 100-g container as in paragraph (e) of this section

(2) No. 061133 for use of the 100- or 256-g container as in paragraphs (e)(1)(i)(A), (e)(1)(ii), (e)(2), (e)(3), and (e)(4) of this section.

* * * * *

(e) * * *

(2) * * *

(i) *Amount.* 2 grams per gallon (528 ppm) for 2 to 5 days as the sole source of drinking water. Treated turkeys should consume enough medicated drinking water to provide 60 mg tylosin per pound of body weight per day.

* * * * *

(3) * * *

(i) *Amount.* 250 mg per gallon (66 ppm) as the only source of drinking water for 3 to 10 days, depending on the severity of the condition being treated.

* * * * *

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

10. The authority citation for part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

11. In § 522.955, revise paragraphs (b)(3), (d)(1)(ii)(A)(*2*), (d)(1)(ii)(B)(*2*), and (d)(1)(ii)(C) to read as follows:

§ 522.955 Florfenicol.

* * * * *

(b) * * *

(3) Nos. 058005 and 058198 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(1)(ii) of this section.

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(A) * * *

(*2*) *Indications for use.* For treatment of BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni.* For treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus.*

(B) * * *

(*2*) *Indications for use*. For control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni.*

(C) *Limitations*. Animals intended for human consumption must not be slaughtered within 28 days of the last intramuscular treatment. Nos. 000061, 058005, and 058198: Animals intended for human consumption must not be slaughtered within 38 days of subcutaneous treatment. No. 055529: Animals intended for human consumption must not be slaughtered within 33 days of subcutaneous treatment. This product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established in pre-ruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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§ 522.1338 [Amended]

12. In 522.1338, in paragraph (b), remove "086155" and in its place add "043264".

13. In § 522.1662a, revise paragraph (e)(1); add paragraphs (e)(3)(i)(D), (e)(3)(ii)(C), and (e)(3)(iii)(D); and remove paragraphs (e)(3)(iv) through (vii) to read as follows:

§ 522.1662a Oxytetracycline hydrochloride injection.

* * * * *

(e) * * *

(1) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) oxytetracycline hydrochloride.

* * * * *

(3) * * *

(i) * * *

(D) Treatment must be discontinued at least 22 days prior to slaughter. Not for use in lactating dairy animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) * * *

(C) Treatment must be discontinued at least 22 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iii) * * *

(D) Do not administer to laying hens unless the eggs are used for hatching only. Treatment must be discontinued at least 5 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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14. In § 522.2471, revise paragraph (e)(2)(iii) to read as follows:

§ 522.2471 Tilmicosin.

* * * * *

(e) * * *

(2) * * *

(iii) *Limitations.* Animals intended for human consumption must not be slaughtered within 42 days of the last treatment. Not for use in lactating ewes producing milk for human consumption.

§ 522.2690 [Amended]

15. In 522.2690, in paragraph (b), remove "076175" and in its place add "011788".

PART 528-- INTENTIONAL GENOMIC ALTERATIONS IN ANIMALS

16. The authority citation for part 528 continues to read as follows:

Authority: 21 U.S.C. 360b.

17. Revise the heading for part 528 to read as set forth above.

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

18. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc-1, 371.

19. In § 558.95, revise paragraphs (e)(4)(i) and (ii) to read as follows:

§ 558.95 Bambermycins.

* * * * *

(e) * * *

(4) * * *

Bambermycins in grams/ton	Indications for use	Limitations	Sponsors
(i) 1 to 4	Growing beef steers and heifers fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency.	Feed continuously at a rate of 10 to 20 milligrams per head per day.	016592
(ii) 2 to 80	Growing beef steers and heifers on pasture (stocker, feeder, and slaughter), and replacement beef and dairy heifers on pasture: For increased rate of weight gain.	Feed continuously on a hand-fed basis at a rate of 10 to 40 milligrams per head per day in 1 to 10 pounds of supplemental Type C medicated feed.	016592

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20. In § 558.128, revise paragraphs (e)(4)(x), (xi), (xiii), (xxx), and (xxxi) to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(4) * * *

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
		* * * * * * *		
(x) 500 to 2,000 g/ton to provide 10 mg/lb of body weight daily	Laidlomycin, 5	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See §558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xi) 500 to 4,000 g/ton to provide 10 mg/lb of body weight daily	Laidlomycin, 5 to 10	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See §558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
		* * * * * * *		
(xiii) 500 to 1,200 g/ton to provide 10 mg/lb of body weight daily	Lasalocid, 25 to 30	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed continuously in complete feed to provide 10 mg chlortetracycline per lb body weight and not less than 250 mg or more than 360 mg lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
		* * * * * * *		
(xxx) 23.3 to 58.3 g/ton to provide 350 mg/head/day	Laidlomycin, 5	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-	054771

		chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	
(xxxi) 14.6 to 116.7 g/ton to provide 350 mg/head/day	Laidlomycin, 5 to 10	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
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21. In § 558.342, revise paragraph (e)(1)(ii) to read as follows:

§ 558.342 Melengestrol.

* * * * *

(e) * * *

(1) * * *

Melengestrol acetate in mg/head/day	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * * * * *				
(ii) 0.5		Heifers intended for breeding: For suppression of estrus (heat).	Administer 0.5 to 2.0 lb/head/day of Type C feed containing 0.25 to 1.0 mg melengestrol acetate/lb to provide 0.5 mg melengestrol acetate/head/day. Do not exceed 24 days of feeding.	016592, 054771, 058198
* * * * * * *				

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22. In § 558.450:

a. Revise paragraph (e)(4)(i);

b. Redesignate paragraphs (e)(4)(ii) through (v) as paragraphs (e)(4)(iii) through (vi);

c. Add new paragraph (e)(4)(ii); and

d. Revise newly redesignated paragraphs (e)(4)(iii) and (vi).

The addition and revisions read as follows:

§ 558.450 Oxytetracycline.

* * * * *

(e) * * *

(4) * * *

Oxytetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 10 mg/lb of body weight daily.	……..	Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. For No. 069254, withdraw 5 days before slaughter. For No. 066104, zero-day withdrawal period.	066104 069254
(ii) 10 mg/lb of body weight daily.	……..	Calves: For treatment of bacterial enteritis caused by *E. coli* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days in milk replacer or starter feed. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. For No. 069254, withdraw 5 days before slaughter. For No. 066104, zero-day withdrawal period.	066104 069254
(iii) 75 mg/head/day		Growing cattle (over 400 lb): For reduction of incidence of liver abscesses.	Feed continuously. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.	066104 069254
		* * * * * * *		
(vi) 0.5 to 2.0 g/head/day	……..	Cattle: For prevention and treatment of the early stages of shipping fever complex.	Feed 3 to 5 days before and after arrival in feedlots. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.	066104 069254

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23. In § 558.455:

a.Redesignate paragraphs (e)(1)(ii) through (iv) as paragraphs (e)(1)(i) through (iii);

b. Redesignate paragraphs (e)(2)(ii) through (iv) as paragraphs (e)(2)(i) through (iii);

c. Revise paragraphs (e)(3) and (4); and

d. Add paragraph (e)(5).

The revisions and addition read as follows:

§ 558.455 Oxytetracycline and neomycin.

* * * * *

(e) * * *

(3) *Swine.* It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount		Limitations	Sponsors
(i) To provide 10 mg/lb of body weight daily.	Swine: For treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* and treatment of bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter.	066104 069254
(ii) To provide 10 mg/lb of body weight daily.	Breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline.	Feed continuously for not more than 14 d; withdraw 5 d before slaughter.	066104 069254

(4) *Cattle.* It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) To provide 10 mg/lb of body weight daily.	Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial	Feed continuously for 7 to 14 d; in feed or milk replacers. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been	066104 069254

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
	enteritis) caused by *E. coli* susceptible to neomycin.	established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter.	
(ii) To provide 10 mg/lb of body weight daily.	Calves (up to 250 lb): For treatment of bacterial enteritis caused by *E. coli* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d; in milk replacers or starter feed. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter.	066104 069254
(iii) To provide 75 mg/head/day	Growing cattle (over 400 lb): For the reduction of the incidence of liver abscesses.	Feed continuously.	066104 069254
(iv) To provide 0.5 to 2.0 g/head/ day	Cattle: For prevention and treatment of the early stages of shipping fever complex.	Feed 3 to 5 d before and after arrival in feedlots. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.	066104 069254

(5) *S.* It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) To provide 10 mg/lb of body weight daily.	Sheep: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Withdraw 5 d before slaughter.	66104 069254
(ii) [Reserved]			

24. In § 558.575, revise paragraphs (e)(3)(iv) and (v) to read as follows:

§ 558.575 Sulfadimethoxine and ormetoprim.

* * * * *

(e) * * *

(3) * * *

Sulfadimethoxine and ormetoprim amount	Indications for use	Limitations	Sponsors
* * * * * * *			
(iv) 630 to 3780 g/ton sulfadimethoxine and 126 to 756 g/ton ormetoprim to provide 50 milligrams (mg) of active ingredients per kilogram of body per day	Salmonids: For the control of furunculosis in salmonids (trout and salmon) caused by *Aeromonas salmonicida* strains susceptible to sulfadimethoxine and ormetoprim combination.	Administer for 5 consecutive days. Withdraw 42 days before release as stocker fish or slaughter.	015331
(v) 630 to 3780 g/ton sulfadimethoxine and 126 to 756 g/ton ormetoprim to provide 50 mg of active ingredients per kilogram of body per day	Catfish: For control of enteric septicemia of catfish caused by *Edwardsiella ictaluri* strains susceptible to sulfadimethoxine and ormetoprim combination.	Administer for 5 consecutive days. Withdraw 3 days before slaughter or release as stocker fish.	015331

Dated: November 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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